REMARKS

Reconsideration of this application is respectfully requested in view of the foregoing amendments and the following remarks. Claims 1-32 were pending in this Application. Claim 1 has been amended, claim 25 has been canceled, and claims 21-24 remain withdrawn. Accordingly claims 1-20 and 26-32 are presently under examination. Support for the amendments may be found, for example, in the original claims, and in the specification at page 7 lines 26-28. No new matter has been introduced.

In the Office Action:

- Claims 20, 26 and 31 were not rejected.
- Claims 1-8, 13-19, 25 and 27-29 were rejected under 35 U.S.C. §103(a) as obvious over Ohki (U.S. Patent Publication 2002/0187187; hereinafter "Ohki") in view of Bock et al. (U.S. Patent No. 6,869,948; hereinafter "Bock") as evidenced by http://science.kosmix.com/topic/hydrated_silica (no copy provided; hereinafter "Kosmix").
- Claims 1-19, 25, 27-30 and 32 were rejected under 35 U.S.C. §103(a) as obvious over Skinhøj et al. (U.S. Patent 6,599,529; hereinafter "Skinhøj") in view of Bock, Ouali et al. (U.S. Patent No. 6,183,779; hereinafter "Ouali") and Robinson et al. (U.S. Patent No. 6,071,539; hereinafter "Robinson").

Applicants respectfully traverse the rejections and submit that all claims pending herein are in condition for Allowance, for the reasons set forth below.

Office Action Incomplete: Status of Claims 20, 26 and 31 Unclear

Applicants note that the Office Action is incomplete because claims 20, 26 and 31 were not rejected, and no indication was made that these claims are presently allowable. Applicants' undersigned representative Ms. Cohan contacted Examiner Purdy regarding the deficiency of the Office Action on multiple occasions, including via telephone on April 21 and April 26, 2011. On April 26, 2011 Examiner Purdy stated that he would issue a Supplemental Office Action to correct the deficiency, however as of May 25, 2011 he had not done so.

Ms. Cohan attempted to contact Examiner Purdy on several occasions in May 2011 but was unable to either reach him via telephone or leave him a voicemail message due to his apparent removal from the USPTO telephone system. On May 24, 2011, Ms. Cohan spoke to Supervisory Patent Examiner Sharmila Landau, who confirmed that the USPTO telephone system was experiencing difficulties where Examiners could not be reached by telephone and could not access their voicemail. SPE Landau stated that she would contact Examiner Purdy regarding

the Application, but recommended that Applicants proceed to file their response to the Office Action despite its defects. SPE Landau also confirmed that due to the deficiency in the Office Action, the next Office Action for this Application cannot be made Final. In accordance with SPE Landau's recommendation, Applicants have filed this response notwithstanding the deficient Office Action.

Ohki Is Not Prior Art To The Present Application

As an initial matter, Applicants respectfully submit that Ohki is not prior art to the present application, because Applicants have perfected their priority claim under 35 U.S.C. § 119(a), and have submitted an English language translation of the priority document.

The present Application claims priority under 35 U.S.C. §119(a) to an earlier-filed German application (Application No. 102 50 081) filed on October 25, 2002, which provides full support for the presently claimed invention for purposes of 35 U.S.C. §112. The priority claim to the German application was made in the present Application on October 27, 2003 in an Application Data Sheet filed with the Office, and at that time the German application was properly identified by application number, filing authority, and filing date. A certified copy of the priority document was filed with the Office on October 27, 2003. Thus, the priority claim was perfected as of October 27, 2003. Pursuant to 37 CFR §1.55(a)(4), an English language translation of the priority document, along with a statement that the translation is accurate, is required if the foreign priority date is used to overcome the date of a reference relied upon by the Examiner. Applicants are preparing such a translation and will submit it to the Office shortly.

Because Applicants are entitled to rely upon their foreign priority date of October 25, 2002, and this date antedates the publication of Ohki on December 12, 2002, ***Ohki cannot be 35 U.S.C. § 102(a) or (b) art to the present Application***.

Ohki now qualifies as prior art to the present application only under 35 U.S.C. § 102(e), and thus ***cannot be used*** to preclude the patentability of the present invention if it was, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. 35 U.S.C. § 103(c); *see also* MPEP § 706.02(l)(2), Part II. Applicants hereby submit that ***the present application and Ohki were, at the time the claimed invention of the present Application was made, owned by or subject to an obligation of assignment to the same entity***, C.H. Boehringer Sohn AG & Co. KG. C.H. Boehringer Sohn AG & Co. KG is the common owner because it wholly owns Boehringer Ingelheim Vetmedica GmbH

(the assignee of the present Application), and Boehringer Ingelheim International GmbH (the assignee of Ohki). Accordingly, Ohki is not prior art to the present Application.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-8, 13-19, 25 and 27-29 over Ohki, because the rejections have been obviated based on the disqualification of Ohki as prior art.

Obviousness Rejection over Ohki

Claims 1-8, 13-19, 25 and 27-29 were rejected under 35 U.S.C. §103(a) as obvious over Ohki, Bock and Kosmix. Applicants respectfully traverse, on the grounds that primary reference ***Ohki is not prior art to the present application***, as explained in the preceding argument. Accordingly, withdrawal of the rejection is respectfully requested.

Applicants also note that the Office's reliance on Kosmix is both factually and legally improper. First, the Office argues that "Kosmix teaches that hydrated silica (silicon dioxide) is often used for its ability to dissolve in water." Office Action at page 3. The Office did not provide a copy of Kosmix. On April 21, 2011 the undersigned navigated to the web address provided by the Office, and obtained a web page containing various snippets of information. A printout of the website is provided with this reply. As can be seen from the printout, Kosmix discloses very little useful information regarding hydrated silica, and merely contains a few sentence fragments. *See, e.g.*, page 7 of the attached printout. Applicants cannot find any disclosure in Kosmix regarding how "often" hydrated silica is used for any particular purpose.

Second, the Office's reliance on Kosmix as proving the "usage" of hydrated silica in the art is not a citation of Kosmix as a purely factual reference, and thus Kosmix must be prior art (i.e., it must antedate Applicants' priority date). However, even if Kosmix did contain some pertinent disclosure, nothing available on the printout indicates anything about the public availability date of such information. Furthermore, as noted on the Kosmix web site, Kosmix was not founded until 2005 - ***three years after Applicants' priority date***. Thus, the earliest possible date for any disclosure on Kosmix is well after Applicants' priority date and so Kosmix is not prior art and cannot be used as a reference to show how hydrated silica was used in 2002.

Obviousness Rejection over Skinhøj

Claims 1-19, 25, 27-30 and 32 were rejected under 35 U.S.C. §103(a) as obvious over Skinhøj in view of Bock, Ouali and Robinson. To the extent this rejection might still be applied to claims presently pending in this application, it is respectfully traversed, and reconsideration is requested.

A. The Claimed Invention

Claim 1 has been amended to recite ***water soluble granules*** comprising meloxicam and a salt forming agent, wherein 5 g of said granules ***dissolve*** in 100mL of demineralized water ***in about 1 minute*** to form a clear solution. This new limitation regarding the speed of dissolution of the granules is not taught by any of the cited prior art references,. Accordingly, claim 1 and all its dependents are in condition for Allowance.

With respect to claims 27-30, the Office argued that Applicants have failed to define what compounds materially affect the basic and novel characteristics of the claimed invention. Office Action at page 4. Applicants respectfully disagree.

The situation here is highly analogous to the exemplary *AK Steel Corp.* case cited in MPEP § 2111.03. In *AK Steel*, the patent claimed a "coating metal consisting essentially of aluminum." *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1237 (Fed. Cir. 2003). The Federal Circuit examined the specification of the patent, which "states that good wetting is the goal of the invention" and also states that "'silicon contents in the coating metal should not exceed about 0.5% by weight'". In view of these statements in the specification, the Federal Circuit held that "silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention." *Id.* at 1240.

Like the patent in *AK Steel*, ***the present Application states a goal: water soluble granules containing meloxicam***. For example, the present Application is entitled "Water-Soluble Meloxicam Granules" and discloses that:

- "meloxicam...does not dissolve readily in water" (page 1 lines 19-20);
- "The aim of the present invention is therefore to develop a granulated form of meloxicam which can be administered to the animals by mixing it into their drinking water" (page 1 line 30 through page 2 line 1);
- "The invention therefore relates to water soluble meloxicam granules..." (page 2 line 10);
- "The meloxicam granules according to the invention have a number of advantages over existing preparations. ... Because of the good solubility of the meloxicam granules according to the invention in water..." (page 2 lines 15-21); and
- "The total solubility of the granules in water ensures optical control of a totally dissolved active substance..." (page 2 lines 26-27).

Further, 22 of the original 24 claims specifically recited the term "water soluble" in the claims.

Just as the Federal Circuit in *AK Steel* was able to determine what "materially affects the basic and novel properties of the invention" by "look[ing] no further than the specification", the

person skilled in the art here would understand that the goal of the present Application is to achieve water solubility of meloxicam granules, and thus that the "basic and novel characteristics" of the claimed invention are ***water-soluble*** granules of meloxicam.

Accordingly, for the claims that recite water soluble particles "consisting essentially of" meloxicam and other components (claims 27-32), the person skilled in the art would understand that the addition of insoluble components that would, by composition or amount, affect this basic and novel water-solubility of the claimed granules is excluded by the use of the term "consisting essentially" in the claims.

B. The Rejection

The Office contends that Skinhøj teaches "rapid release particles" that include an NSAID, that Bock discloses granular formulations of meloxicam salts, that Ouali teaches various fillers, and that Robinson teaches granules containing sweeteners and flavors. Applicants respectfully disagree with the Office that Skinhøj, either alone or in combination with the secondary references, teaches or suggests the claimed methods, because the cited art fails to teach or suggest water soluble granules, or indeed any granules containing meloxicam salts.

With respect to Skinhøj, the Office admits that it fails to teach water-soluble granules, meloxicam salts, sweeteners or flavorants. However, the Office argues that Example 1 of Skinhøj teaches "rapid release" particles comprising the NSAID lornoxicam. The Office also argues that Bock teaches a granular formulation of meloxicam having a high amount of carrier and comprising a meloxicam salt. Office Action at page 5. Applicants respectfully disagree that such disclosures, whether alone or in combination, teach or suggest the claimed invention.

The particles of Skinhøj, like those of Bock, contain a high amount of insoluble material, and therefore are not water soluble. Example 1 of Skinhøj recites a formulation that contains over 26% insoluble ingredients such as microcrystalline cellulose (17%), lornoxicam (9%) and carmellose sodium (0.5%). The granules of Bock in Examples 6 and 7 contain over 51% (Example 6) and 67% (Example 7) insoluble ingredients (not even counting the additional 1.7 to 4.2% insoluble meloxicam), such as cross-linked polyvinylpyrrolidone, microcrystalline cellulose and silicon dioxide. Thus, ***it is not chemically possible for such granules to be water soluble***. *See, e.g.*, Declaration of Dr. Martin Folger submitted on May 11, 2009, at paragraphs 15, 20. Nor do any of the granules of Skinhøj or Bock comprise a salt of meloxicam. The meloxicam salts disclosed in Example 1 and 7 of Bock are not in granular form.

Because Skinhøj and Bock both fail to teach water-soluble granules, neither reference can teach or disclose the claimed formation of a clear solution in about 1 minute (a solution

requires solubility). The Office argues that Skinhøj teaches "rapid release particles", however it is clear from reading Example 1 of Skinhøj that "rapid" means that release "is almost accomplished within about 1 hour." *See* Skinhøj at col. 33 lines 46-48. The granules of Bock require about an hour to achieve ***release*** of meloxicam, see Bock at FIG. 3, however nothing is mentioned about whether such "release" is in any way equivalent to the claimed formation of a solution. Accordingly, Skinhøj and Bock fail to teach or disclose that 5 g of their granules dissolve in 100mL of demineralized water in about 1 minute to form a clear solution.

Skinhøj and Bock thus fail to teach or suggest water soluble granules comprising meloxicam salts, or such granules wherein 5 g of the granules dissolve in 100mL of demineralized water in about 1 minute to form a clear solution. The secondary references fail to supplement these deficiencies. Neither Ouali nor Robinson teach or suggest water soluble granules of any type, meloxicam salts in granular form, or meloxicam granules wherein 5 g of the granules dissolve in 100mL of demineralized water in about 1 minute to form a clear solution. Thus, even the combination of Ouali and Robinson with both Skinhøj and Bock fails to teach or suggest the present independent claims.

The Office argues that Ouali "teaches that microcrystalline cellulose can be interchanged with water-soluble agents such as mannitol, urea, sucrose, ...[and] teaches that microcrystalline cellulose is functionally equivalent to water-soluble agents such as lactose..." Office Action at page 7. Applicants respectfully disagree. ***Ouali does not teach that microcrystalline cellulose is "functionally equivalent" to lactose or other water-soluble agents***. In fact, Ouali specifically notes the ***functional differences*** between the ***insoluble*** microcrystalline cellulose and ***soluble*** materials such as lactose: for the function of water solubility, microcrystalline cellulose is ***not equivalent*** to lactose. Moreover, even if it did teach a "functional equivalence" (and Applicants do not concede this), Ouali still fails to teach or suggest water soluble granules of any type, meloxicam salts in granular form, or water soluble meloxicam granules wherein 5 g of the granules dissolve in 100mL of demineralized water in about 1 minute to form a clear solution. Further, even if the person skilled in the art were to replace cellulose with lactose, such substitution would still not result in the claimed combinations, because the particles of Skinhøj and Bock contain other insoluble ingredients. Thus, even the combination of Ouali with the other references fails to teach or suggest the present claims.

With respect to the various dependent claims, the Office acknowledges that neither Skinhøj or Bock teaches sweeteners or flavorants. The Office argues that Robinson teaches that "granules are to comprise taste-masking agents such as sweeteners like aspartame", and that "[t]he granular particles comprise 5% by weight of aspartame", Office Action at page 6, and points to Table 3 (column 20) of Robinson for support. Applicants respectfully disagree. ***Robinson does not teach granules comprising sweeteners such as aspartame or flavorings***. Table 3 (and indeed all of Example 3) of Robinson teaches a ***tablet formulation*** comprising a mixture of effervescent granules with multiple ingredients including aspartame and grape flavor. The cited section of Robinson is set forth to the right.

Table 3 is presented to demonstrate effevesing granules in a convenient dose form. In this table, the dose form is a tablet. However, any number of other dose forms may be employed in providing a patient ready therapeutic of the present granulations.

TABLE 3

Hot-Melt Extruded - Effervescent Couple
(Tablet Formulations)
Effervescent tablets contains effervescent granules prepared by hot-melt extrusion.

Tablet Formulation H % w/w	Excipient	Tablet Formulation I % w/w
32.0	APAP	32.0
20.0 (formulation y)	EG	25.0 (granulation s)
28.0	Mannitol, fine powder	26.0
8.0	Emcocel ® LMSO	5.0
5.0	Kollodion ® CL	5.0
5.0	Aspartame	5.0
0.7	Flavor, grape	0.7
0.4	Lake, lavender	0.4
0.3	Cab-O-Sil ® MSP	0.3
0.6	Magnesium Stearate	0.6

Generally, the listed ingredients are thoroughly mixed in a low relative humidity environment to form a tableting mixture. All the ingredients will generally pass through a 20 mesh screen. The tableting mixture is tableted in a conventional tableting press.

As explained in Robinson, "[a]ny of the effervescent granules detailed here as granules A through S may be employed where effervescent granule (EG) is indicated in the following tablet formulations." Robinson at col. 19, ll. 22-26. None of the effervescent granules comprise aspartame or flavorings. ***Robinson thus fails to teach the incorporation of either a sweetener like aspartame or a flavor in a granule.*** Accordingly, even the combination of Robinson with the other references fails to teach or suggest the present claims.

With respect to claims 27-30 and 32, the phrase "consisting essentially of" excludes the addition of components that materially affect the basic and novel characteristics of the claimed invention, i.e., the water solubility of the claimed meloxicam granules. Thus, insoluble components may not be added to these claimed compositions. The cited references, however, teach particles having multiple insoluble components, as shown below.

For claim 27, the chart below illustrates that the particles in the cited references contain at most ***two*** of the five claimed components, and contain *substantial amounts* (26.5 to 71.8%) *of insoluble components* that are excluded from the claim due to the use of the "consisting essentially of" transitional phrase.

Claim 27. Water soluble granules consisting essentially of:	Skinhoj (Example 1; Table 1)		Bock Example 6: Insoluble tablet formulation (compressed from granules)		Bock Example 7: Insoluble capsule formulation containing granulated meloxicam	
soluble meloxicam (in salt form)	**none**		**none**		**none**	
a salt forming agent	**none**		**none**		**none**	
water soluble binder	pregelatinized starch (60 g; 10%); maltodextrin (12g; 2%)	12%	**none**		soluble polyvinyl-pyrrolidone (10.5 mg; 5.8%)	5.8%
sugar or sweetener	**none**		**none**		**none**	
water soluble carrier	lactose	52.5%	lactose 205.0 mg	45.6%	lactose 23.5 mg	13.1%
(optional) water soluble flavoring agent	**none**		**none**		**none**	
	polysorbate 20 (soluble)	9%	Mg stearate 4.5 mg (soluble)	1%	sodium citrate & Mg stearate 16.7 mg (soluble)	9.3%
	Insoluble ingredients: lornoxicam (54 g; 9%); microcrystalline cellulose (102 g; 17%); carmellose sodium 3g (0.5%) (insoluble)	**26.5 %**	***insoluble ingredients:*** meloxicam (7.5 mg; 1.7%); micro-crystalline cellulose & cross-linked polyvinyl-pyrrolidone (232.5 mg; 51.7%)	**53.4 %**	***Insoluble ingredients:*** meloxicam (7.5 mg; 4.2%); microcrystalline cellulose & cross-linked polyvinyl-pyrrolidone (118.3 mg; 65.7%); silicon dioxide (3.5 mg; 1.9%)	**71.8 %**

For claim 32, the chart below illustrates that ***only one particle from the cited references contains even a single claimed component***, and contain *substantial amounts* (26.5 to 71.8%) *of insoluble components* that are excluded from the claim due to the use of the "consisting essentially of" transitional phrase.

Claim 32. Water soluble granules consisting essentially of:	Skinhoj (Example 1; Table 1)		Bock Example 6: Insoluble tablet formulation (compressed from granules)		Bock Example 7: Insoluble capsule formulation containing granulated meloxicam	
soluble meloxicam (in salt form)	**none**		**none**		**none**	
meglumine	**none**		**none**		**none**	
HPMC	**none**		**none**		**none**	
soluble povidone	**none**		**none**		soluble polyvinyl-pyrrolidone (10.5 mg; 5.8%)	5.8%
glucose monohydrate	**none**		**none**		**none**	
	Soluble: polysorbate 20; pre-gelatinized starch (60 g; 10%); maltodextrin (12g; 2%); lactose (52.5%)	73.5%	Soluble: Mg stearate 4.5 mg; lactose 205.0 mg (45.6%)	46.6%	Soluble: sodium citrate & Mg stearate (16.7 mg; 9.3%); lactose (23.5 mg; 13.1%)	22.4%
	Insoluble ingredients: lornoxicam (54 g; 9%); microcrystalline cellulose (102 g; 17%); carmellose sodium 3g (0.5%) (insoluble)	**26.5 %**	***insoluble ingredients:*** meloxicam (7.5 mg; 1.7%); micro-crystalline cellulose & cross-linked polyvinyl-pyrrolidone (232.5 mg; 51.7%)	**53.4 %**	***Insoluble ingredients:*** meloxicam (7.5 mg; 4.2%); microcrystalline cellulose & cross-linked polyvinyl-pyrrolidone (118.3 mg; 65.7%); silicon dioxide (3.5 mg; 1.9%)	**71.8 %**

In addition, a prima facie case of obviousness has not been established because the Office has not provided any support for the conclusion that there existed at the time of the invention an apparent reason to modify the insoluble granules of Skinhøj or Bock to alter their solubility. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *See KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727,

1740-41, 82 USPQ2d 1385, 1396 (2007); *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). *See also* MPEP § 2141. The Office's cited rationale that a person of ordinary skill in the art could combine the cited references "with a reasonable expectation of success" is just such a conclusory statement.

As explained above, ***none of the cited references teaches water soluble granules of any type***, let alone water soluble granules containing meloxicam salts wherein 5 g of the granules dissolve in 100mL of demineralized water in about 1 minute to form a clear solution. As shown by the two tables illustrating the differences between claims 27 and 32 and the insoluble Skinhøj or Bock, the person skilled in the art would need to change almost all or all components of the prior art particles in order to achieve the claimed invention. Such radical alterations are not within the realm of simple substitutions.

The Office claims that it is merely "ordinary skill" to turn the insoluble particles of Skinhøj or Bock into soluble particles having the claimed ability to form a solution in about 1 minute, but provides no rational underpinning for this bold statement that goes far beyond what any of the cited references teaches or even suggests. The skilled artisan would not have expected that the insoluble Skinhøj or Bock particles could be modified in the absence of any guidance in the art to result in a water soluble granule containing meloxicam salts wherein 5 g of the granules dissolve in 100mL of demineralized water in about 1 minute to form a clear solution, let alone with any degree of predictability.

Without using Applicants' claimed invention as a roadmap, ***there is no guidance for the artisan to modify Skinhøj or Bock's granules***. It is well-established law that obviousness cannot be proven using hindsight, that is, it "is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992). *See also In re Gorman*, 933 F.2d 982, 987 (Fed. Cir. 1991) ("It is impermissible ... simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps."). This law has not been obviated by the Supreme Court's *KSR* decision. As explained in the post-*KSR* case of *Takeda Chemical Indus. v. Alphapharm Pty.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007), it "remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." No such reason is found here.

Hence, the cited references taken alone or in combination do not teach, suggest, or make obvious the present invention, and Applicants respectfully request that the rejection be

withdrawn. In view of the foregoing, all of the claims in this case are believed to be in condition for allowance. Should the Examiner have any questions or determine that any further action is desirable to place this application in even better condition for issue, the Examiner is encouraged to telephone Applicants' undersigned representative.

Dated: May 25, 2011

Respectfully submitted:

/June E. Cohan/

June E. Cohan
Registration No. 43,741
Attorney for Assignee

EDELL, SHAPIRO & FINNAN, LLC
1901 Research Boulevard, Suite 400
Rockville, MD 20850
Telephone: 301.424.3640
Facsimile: 301.762.4056

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